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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FORMAN, BETTY J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 04/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/777,553

Applicant(s)

PERBOST ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**FINAL ACTION**

1. This action is in response to papers filed 10 February 2003 containing a Response to the Office Action of 3 October 2002, an amendment to the specification and a Terminal Disclaimer. The Amendment and the Terminal Disclaimer have been entered. Applicant's response has been thoroughly reviewed and is discussed below.

The previous rejection under the judicially created doctrine of obviousness-type double patenting over U.S. Patent No. 6, 184,347 is withdrawn in view of the Terminal Disclaimer.

The previous rejections under 35 U.S.C. 112, second paragraph are withdrawn in view of Applicant's comments.

The previous rejections under 35 U.S.C. 102(b) are maintained.

All of the arguments have been thoroughly reviewed and are discussed below.

Claims 21-36 are under prosecution.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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3. Claims 21-23 and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Weiler et al (Analytical Biochemistry, 1996, 243: 218-227).

Regarding Claim 21, Weiler et al disclose the method used during the solid-state synthesis of surface-bound polymers at different locations on a solid substrate to form an array the method comprising: selecting a reactive wash solution that is not reactive toward any nascent polymers bound to the solid substrate but that reacts with and deactivates the reactive reagents and that is miscible with the reaction solution, and applying the reactive solution to the surface of the solid substrate in order to react with and deactivate any unreacted reactive reagents (page 220, left column, first full paragraph; page 222, Table 1 and right column-page 223).

Regarding Claim 22, Weiler et al disclose the method wherein the reaction solution includes reactive monomers and catalyzing reagent that catalyzes the coupling of reactive monomers to the nascent polymers (page 220, left column, first full paragraph; page 222, Fig. 4 and Table 1 and right column through page 223).

Regarding Claim 23, Weiler et al disclose the method wherein the reactive monomers are deoxynucleoside phosphoramidites and the polymers are oligonucleotides (Abstract and page 219, left column, first full paragraph).

Regarding Claim 30, Weiler et al disclose a method of fabricating an array of polymers located at features of the array, the method comprising: coupling a reactive monomer to a nascent polymer bound to the surface of a solid substrate comprising: applying monomer molecules and reagent required to catalyze the coupling of the monomer with the nascent polymer and applying a reactive wash solution to the surface of the solid substrate to react with and deactivate any remaining reactive monomers on the surface of the substrate (Abstract, page 220, left column, first full paragraph; page 222, Table 1 and right column-page 223 and Fig. 6).

Regarding Claim 31, Weiler et al disclose the method wherein the reactive monomers are deoxynucleoside phosphoramidites and the polymers are oligonucleotides (Abstract and page 219, left column, first full paragraph).

#### **Response to Arguments**

4. Applicant argues that Weiler does not disclose the instant invention. Applicant points to figure 6 of U.S. Patent No. 6,184,347 wherein first, acetonitrile is a wash agent that does not react with and deactivate any reacted reactive reagents and second, the polypropylene sheet is washed with DMF, presumably removing unreacted reagents and potentially causing the blooming that the '347 invention is directed to prevent and only as a second and separate wash step is methanol used. Applicant argues that the method of Weiler does not conform to the instant invention because they do not teach a solution applied to removed unreacted reagents and is reactive towards and deactivates unreacted reagents preventing the reactive reagents from migrating to portion of the substrate to which they were not applied and where they can undergo undesirable reactions. Applicant further argues that Weiler suggests using a different combination of capping reagents that do not include tetrahydrofuran and teaches nothing about wash reagents. The arguments have been considered but are not found persuasive because the instant claims are drawn to a method for removing a reaction solution including unreacted reagent from the surface of the solid support. The method steps include 1) selecting a reactive wash solution that is not reactive toward any nascent polymers on the support but reacts with and deactivates the reactive reagents and is miscible with the reaction solution and 2) applying the reaction wash solution to the surface "in order to" react with, and deactivate any unreacted reactive reagents. The claims do not recite limitations of tetrahydrofuran. Furthermore, the claims do not recite limitations of reacting or deactivating because the broad claim language "in order to" merely suggests that reacting and deactivating could occur.

Weiler discloses the instantly claimed 1) selecting a reactive wash solution that is not reactive toward any nascent polymers bound to the solid substrate but that reacts with and deactivates the reactive reagents and that is miscible with the reaction solution, and 2) applying the reactive solution to the surface of the solid substrate in order to react with and deactivate any unreacted reactive reagents i.e. to react with and deactivate residual methylamino groups either a capping solution is applied or in the alternative DMF, methanol and acetone are applied (page 220, left column, first full paragraph; page 222, Table 1 and right column-page 223). As such, Weiler select and apply a washing solution that reacts with and deactivates reactive reagents.

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Applicant's arguments regarding the flow chart presented in figure 6 of the '347 patent is not relevant to the instant claims because the instant claims merely recite steps of selecting and applying but do not recite the limitations illustrated in the patent figure.

The courts have stated that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that the instant invention is not concerned with capping reagents or capping steps but is instead directed to a reactive wash solution for removing previously applied reaction solution from the surface of the microarray. The argument has been considered but is not found persuasive because as stated above, the instantly rejected claims are broadly drawn to a method comprising the steps of selecting and applying a wash solution. The rejected claims are not limited to removing a reaction solution **or** a microarray. Furthermore, the solution of Weiler is applied to the solid support and removes reagents from the solid support (i.e. washes). As such, the teaching of Weiler is encompassed by the instant method as broadly claimed.

Finally, Applicant argues that it is improper to extend assumptions about the reactivities of reagents without a teaching that the reagents show similar reactivities. While not explicitly stated, this argument is interpreted by the examiner to say that Weiler does not teach that their reagents are washing reagents that react with and deactivate reagents. This argument is not found persuasive because Weiler specifically teaches that their solution reacts with and deactivates residual methylamino groups is either a capping solution or in the alternative DMF, methanol and acetone (page 220, left column, first full paragraph). Therefore, Weiler specifically teaches the properties of the instantly claimed wash solution.

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re*

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*Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 30-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,300,137. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods comprising steps of coupling, selecting and applying reactive wash solutions to the surface of a solid substrate to react with and deactivate any unreacted reactive reagents and differ only in the patent claims recite additional steps of capping unreacted groups and repeatedly applying solutions. However, the instant claims are drawn to the similar method comprising coupling and applying wherein the open claim language "comprising" encompasses the additional patent method steps. As such, the instantly broadly claimed methods are a genus of the patent claims. The courts have stated that a genus is obvious in view of the teaching of a species see *Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Therefore the instantly claimed method comprising coupling and applying (i.e. genus) is obvious in view of the patent method comprising coupling, capping, applying and repeating (i.e. species).

#### **Response to Arguments**

7. Applicant argues that Earhart is directed to using covering volumes during synthesis in a method comprising various rinse steps but the method does not claim a reactive wash solution. The argument has been considered but is not found persuasive because the '137 claims are drawn to a method of synthesis comprising rinsing (as Applicant acknowledges). The '137 disclosure describes the claimed rinsing solution as a solution which reacts with and deactivates unreacted reagents. As such, the '137 "rinsing" solution encompasses the instantly claimed washing solution. The rejection is maintained.

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After excess, unreacted protected deoxynucleoside phosphoramidite and activator are removed by washing, any unreacted 5'-hydroxyl groups 508 of substrate-bound oligonucleotides are acetylated 510 by application of a CAP A (tetrahydrofuran ("THF"), pyridine, and acetic anhydride)/CAP B (methylimidazole in THF) solution. This step is necessary because the previous oligonucleotide elongation reaction does not proceed to 100% completion, and it is desirable to terminate any unreacted nucleotides by acetylation so that oligonucleotides with incorrect sequences are not produced in subsequent synthetic steps. After the CAP A/CAP B solution is removed by washing with acetonitrile, the phosphite triester group 512 is oxidized to a phosphotriester group 514 by the addition of I.sub.2, THF, pyridine, and H.sub.2O. The steps illustrated in FIG. 5 are repeated to add each additional deoxynucleoside to the 5' end of the growing oligonucleotide.

#### **Response to Comments**

8. The previous rejection of Claims 21-36 under the judicially created doctrine of obviousness-type double patenting over claims 1-15 of U.S. Patent No. 6,184,347 is withdrawn in view of the Terminal Disclaimer.
9. The previous rejection of Claims 21-36 under the judicially created doctrine of obviousness-type double patenting over claims 4-24 of U.S. Patent No. 6,451,998 is withdrawn in view of Applicant's comments.

#### **Prior Art**

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:



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McGall et al (U.S. Patent No. 6,147,205, filed 5 March 1997) teach solid-state synthesis of surface-bound polymers at different locations on a solid substrate to form an array the method comprising: a reactive wash solution (i.e. methanol) (Column 2, line 53-Column 3, line 19 and Column 8, lines 56-65).

Hirschbein et al (U.S. Patent No. 5,824,793, issued 20 October 1998) teach solid-state synthesis of surface-bound polymers comprising: selecting a reactive wash solution that reacts with and deactivates the reactive reagents (i.e. methanol), and applying the reactive solution to the surface of the solid substrate in order to react with and deactivate any unreacted reactive reagents (Column 9, lines 20-46, Column 12, lines 8-20; and Example 7, Column 29, lines 45-61).

**11. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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**Conclusion**

12. No claim is allowed. Claims 24-29 are free of the prior art of record and may be placed in condition for allowance following resolution of the above rejections.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.  
Patent Examiner  
Art Unit: 1634  
April 28, 2003